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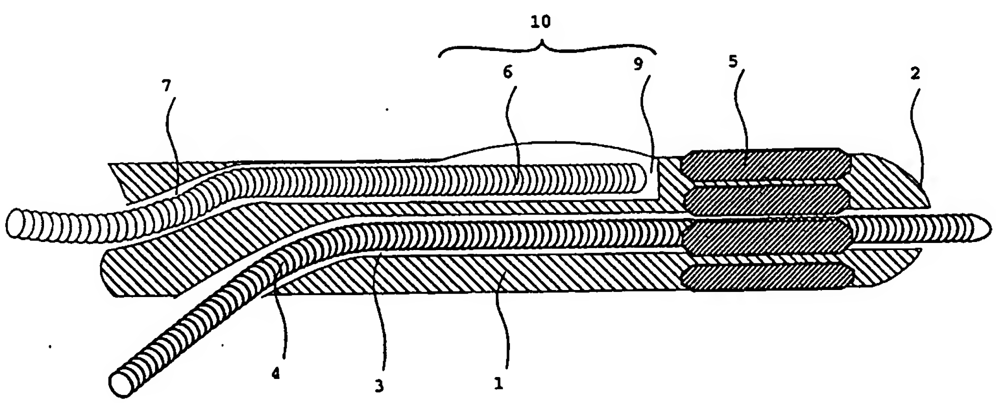
(54) Title: ULTRASOUND CATHETER WITH CAPABILITY OF SIDE IRRADIATION



(57) Abstract

Disclosed is an ultrasound catheter assembly with capability to introduce radioactive source therethrough for invasive ultrasound-guided radioactive treatment of bodily tissue. The catheter comprises side irradiation capabilities for treatment of excentric diseases formation at focal locations.

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Ultrasound Catheter With Capability of Side-Irradiation

Disclosed is an ultrasound catheter assembly with capability to introduce radioactive source therethrough for invasive radioactive treatment of bodily tissue.

Background:

Field of the invention:

The present invention relates to the field of invasive radioactive treatment of bodily tissue, particularly for the treatment of diseased (atherosclerotic) and obstructed vessel segments.

Scope of the problem:

In the cross-sectional view, vessel disease extent can be non-circumferential, thereby demonstrating a segment of the vessel wall that is not-thickened and unaffected by the disease. In coronary vessels, the incidence of eccentric lesions is 69% (Hausmann et al, American Journal of Cardiology 1994 Nov 1; 74(9): 857-63). Since non-proportional irradiation of biological tissue may destroy cells, making it possible, in vessels, for aneurysm development or rupture to occur, this morphological pattern of vessel obstruction deserves selective side irradiation sothat non-diseased wall segments are spared from radioactive traumatization.

Description of the Prior-Art:

A number of catheter assemblies were introduced to address catheter-based radioactive therapeutics. These techniques focus on transcathter introduction of radioactive source to the target segment of the vessel. When positioned in the diseased segment, the radioactive source provides treatment to the lesion.

The following issued documents describe methods to endeavor to treat diseased vessels and to prevent recurrence of disease after cathter treatment (restenosis):

•Dake	US 5,199,939
•Teirstein	US 5,540,659
•Weinstein	US 5,213,561
•Williams	US 5,611,767
•Thornton	US 5,616,114
•Liprie	US 5,618,266
•Diedrich	US 5,620,479
•Passafaro	WIPO 91/02488

The Weinstein et al patent describes method and apparatus with particles or crystals of radioactive catheter materials embedded on a tube provided inside the balloon catheter. During operation, the stenosed segment is irradiated.

The patent to Dake et al shows a radioactive catheter merely indicating that an elongated flexible catheter is transported to the area of the stenosis after a balloon catheter has been withdrawn.

The patent to Teirstein describes a radioactive wire with inflatable balloon or coil-shaped loops, this should provide adequately central position of the radioactive source within the coil balloon and vessel lumen.

The patent issued to Liprie describes an apparatus for treating the location of a stenosis in a blood vessel by introducing a radioactive source into the catheter and is maneuvered to the site of treatment.

The patent issued to Diedrich describes an catheter having a multi-element array of piezoceramic transducers to provide thermal therapy for tumors and benign tissues using heat generated from acoustic energy.

The patents issued to Williams and Thornton demonstrate two different types of inflatable apparatuses for treatment of diseased conduits or vessels. The inflatable devices are filled with a radioactive treatment fluid.

The PCT document to Passafaro et al describes an intravascular probe assembly provided with both ultrasonic imaging and laser ablation capabilities. The device includes a distally positioned rotable housing having an ultrasonic transducer and an optical fiber opertively fixed therein so as to respectively emit acoustic energy and laser radiation along a common path generally parallel to the housing axis. The device provides 360° (circumferential) imaging and laser ablation.

Although efficacious in many clinical situations, none of the aforementioned methods and devices proposes the radioactive energy to be selectively laterally directed so that, within a stenosis caused by non-circumferential disease, the opposite, non-diseased vessel wall segments are spared from radioactive traumatization.

Objectives:

It is an objective of the present invention to provide a catheter assembly for endovascular brachytherapy that is maneuvered and guided by cross-sectional ultrasound vessel imaging generated by ultrasound arrays installed in the catheter.

It is another objective of the present invention to provide a catheter assembly for endovascular brachytherapy with the capability of side (lateral) irradiation of eccentrically (non-circumferentially) located disease in a bodily vessel, duct, conduit etc.

Summary of the invention:

The invention proposes an ultrasound catheter assembly to be introduced in bodily vessels, cavities, conduits, ducts etc. (vessel) with the capability of incorporating a radioactive source in order to provide irradiation treatment to a diseased site.

The proposed catheter has a tapered distal tip.

Ultrasound arrays (multiple transducer elements) system is installed proximate to the distal catheter tip and distal or at the level of the radioactive aperture, providing cross-sectional imaging of tissue.

The catheter incorporates a separate channel for the introduction of a radioactive source (radioactive lumen/channel)

The radioactive lumen passes through the entire length of the catheter. Proximally, the radioactive lumen communicates with a radioactive port for the introduction of a radioactive source during treatment. Distally, the radioactive lumen terminates in a radioactive chamber.

The radioactive chamber is a blind end of the radioactive lumen, which ensures retaining the radioactive source within the catheter. The wall of the radioactive chamber comprises at least segmentally of radioactively-transparent material.

In cross-sectional view of the catheter at the level of the radioactive chamber, a radioactively transparent part of the wall of the radioactive chamber occupies a segment of the exterior catheter surface (side irradiation, radioactive aperture).

The proposed catheter design must demonstrate a circular and uniform external perimeter along the entire length thereof.

Transducer-elements located within the radioactive aperture, or on the circumferential catheter segment which corresponds to the radioactive aperture, send additional electrical signals. These signals are reconstructed as an additional sectorial area indicating the position of the radioactive aperture and is displayed simultaneously on the cross-sectional ultrasonic tissue image.

Figure Descriptions

Fig.1: The Distal Portion Of The Catheter

Figure.2: Cross-sectional Views Through The Various Levels of The Distal Portion Of The Catheter (* electrical cables)

Figure.2E: Another Preferred Embodiment Of the Proposed Invention: The Radioactive Chamber Is Located At the Level Of Ultrasound Arrays (* electrical cables)

Figure 3: The Proposed Catheter During Operation In Coronary Vessels

Fig. 3A: (Ultrasound Image) Area indicating The Position Of Radioactive Aperture

Figure.4: The Relationship Between Radiation Aperture and Ultrasound Arrays

Detailed description of the invention:

The invention proposes a catheter assembly (1) to be introduced in bodily vessels, cavities, conduits, ducts etc. (vessel) in order to selectively apply radioactive treatment to a diseased site located eccentrically (non-circumferentially) on or within the wall of the vessel.

The proposed catheter has a tapered distal tip (2).

The catheter incorporates a channel (3) for guidewire (4), which passes at least partially through the catheter.

Proximate to the distal tip of the catheter, a system of ultrasound arrays (5) (plurality of ultrasound emitting and receiving transducers) are installed to provide cross-sectional ultrasound imaging while introducing and maneuvering of the catheter into the diseased region.

Since the catheter of the proposed invention would act as a conduit to allow a radiation source (6) to be introduced to the site of treatment, it is proposed that the catheter should incorporate a separate channel (7) for safely retaining the radioactive source (radioactive lumen, 7).

The radioactive lumen (7) passes through the entire length of the catheter. Proximally, the radioactive lumen communicates with a radioactive port (8) for the introduction of a radioactive source during treatment. Distally, the radioactive lumen terminates in a

radioactive chamber (9). The radioactive chamber is a blind end of the radioactive lumen, which ensures retaining the radioactive source within the catheter. At least one segment of the wall of the radioactive chamber is made of radioactively-transparent material.

In cross-sectional view of the catheter at the level of the radioactive chamber (Figures 2B, 2E), the radioactive chamber is located at a peripheral, not central position in the catheter, so that the radioactively transparent segment (10) of the wall of the radioactive chamber (9) occupies a segment of the exterior catheter surface (11). This radioactively transparent segment of the exterior catheter surface which is formed by a segment of the radioactive chamber will be regerred to hereunder as radioactive aperture (10). The rest of the catheter circumference is built by the various catheter material and layers. The catheter comprises at least an outer layer with radioactive shielding properties.

Considering the fact that the wall of the radioactive chamber within the radioactive chamber is radioactively transparent, unlike the rest of the catheter material (radioactively shielding material), the above construction ensures a selective lateral transparency for radiation during operation (side irradiation, 10).

During operation and under ultrasound guidance, manually controlled rotability of the catheter is essential for precise positioning of the radiation aperture to engage eccentric disease bulk, so that the non-diseased vessel wall is shielded by the catheter layers located contralaterally to the radioactive aperture.

In order to guarantee precise manual rotation, the proposed catheter design must demonstrate a circular and uniform cross-section along its entire length (figures 2A-E). A circular shape of the catheter cross-section demonstrates equal distribution of tangential forces of manual rotation by the physician at the proximal catheter portion. These (rotational) forces can continuously and precisely be conducted to the distal portion of the catheter due to the circular cross-section (steering for precise positioning of the radioactive aperture).

The ultrasound system:

Frequently, imaging means will be employed to afford a transluminal image of a diseased region of the treatment region. Preferably, ultrasonic transducer(s) (12) will be used to generate the imaging medium. A preferred transducer, its associated circuitry and a preferred mode of operation are described in PCT/WO/94/17734 (eberle et al) incorporated herein by reference.

Accordingly, a system of ultrasound arrays (multiple transducer elements 12) is installed distal or at the level of the radiation aperture.

The transducer elements are responsible for sequentially transmitting and receiving electrical signals in the ultrasonic frequency range, which are then processed and sent (13) to the external signal processing system. Additionally, the present invention proposes that the transducer-elements (14) located within the radioactive aperture, or on the circumferential catheter sector which corresponds to the radioactive aperture, send additional electrical signals (15) to the

external signal processing system. These additional signals can be recognized by an image reconstruction system, which reconstructs an additional sectorial area indicating the position of the radioactive aperture; this position-indicating area of the radioactive aperture can be displayed on the cross-sectional ultrasonic image (Figure 3A).

Such configuration would aid the physician in navigating the vessel wall morphology, detecting eccentric lesions, and thereby steering the radioactive aperture to the proper treatment site (cross-sectional mapping).

The longitudinal-locational relationship between the radioactive chamber/radioactive aperture and the ultrasound array system may vary. Basically, the ultrasound-array-system can be installed distal to the radioactive chamber/radiation aperture; this will aid the physician in locating and targeting the eccentric lesion, before the radioactive aperture is advanced to engage the region of treatment (Figure 3). It would be helpful if the level of radioactive chamber/radioactive aperture is provided with radiopaque markers for additional roentgenologic precision and/or roadmapping.

In another preferred design (Figure 2E), the radioactive chamber/radioactive aperture could be installed within the ultrasound array system; this would aid in monitoring of the radiation aperture position and the treatment region while performing endovascular irradiation simultaneously.

Although the proposed catheter has been explained with respect to treatment of obstructive vessel disease, it is noted that the treatment could be conducted in virtually any conduit, duct, cavity

of the body. This catheter can be also used to treat cancer in various areas of the body, such as the common bile duct, the bladder, the prostate gland, the liver, the lungs etc. employing the technique of side irradiation, with the aid of simultaneous tomographic ultrasound guidance.

Claims:

1. Catheter apparatus with a irradiation capabilities comprising a separate blind-ending lumen, which communicate proxially with a side port for the introduction of radioactive source, distally, the lumen terminates in a dilated, blind-ending segment of the lumen, being located, in cross-sectional view, excentrically sothat a part of the chambers wall occupies a segment of the exterior catheter surface (side irradiation).

2. Catheter apparatus with the capability of ultrasound guided irradiation of atherosclerotically diseased vessel wall segments

3. Catheter apparatus with the capability of side irradiation of atherosclerotically diseased vessel wall segments

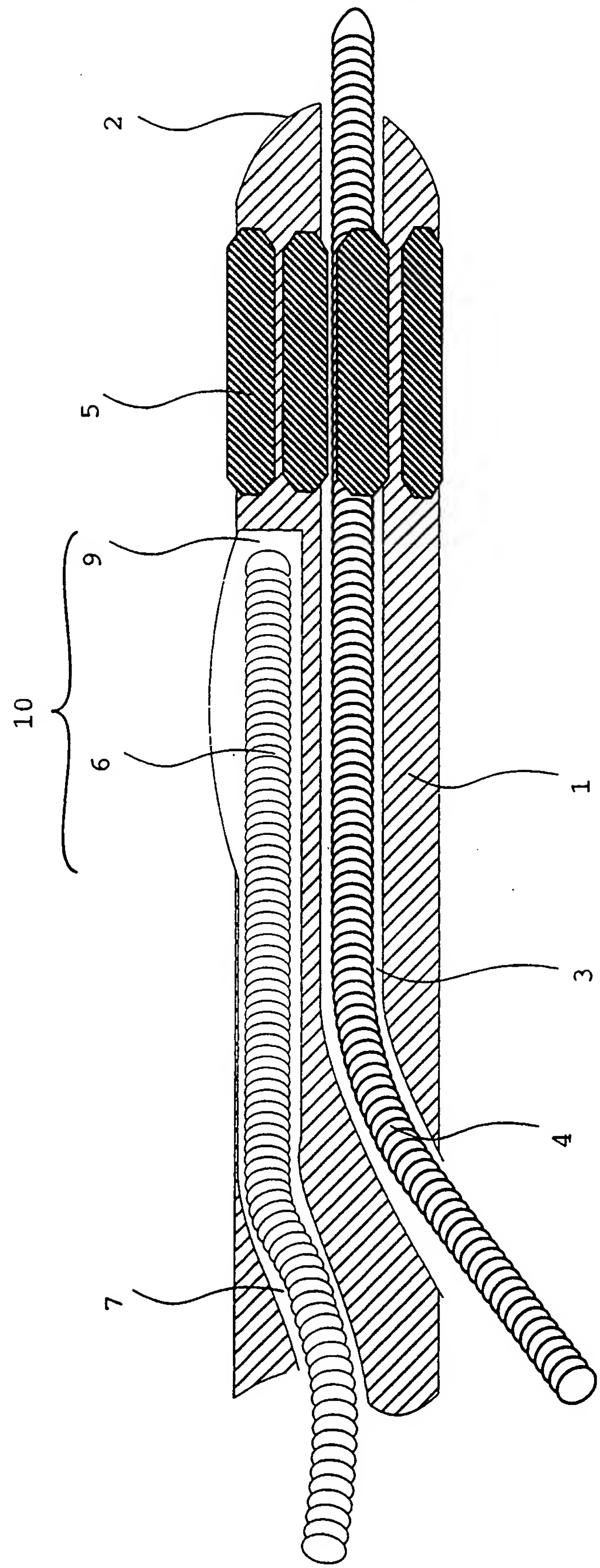


Fig.1

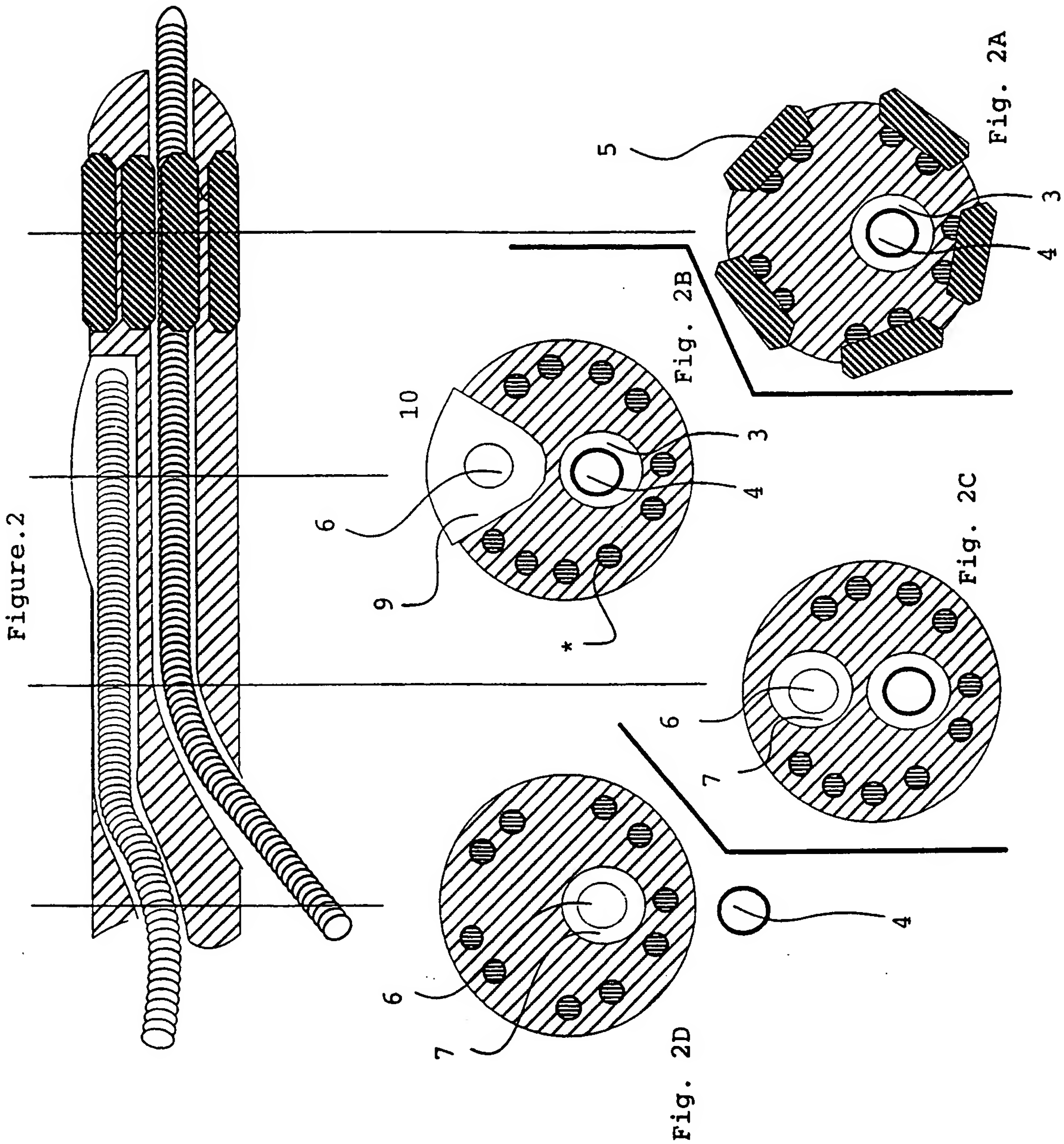


Figure.2

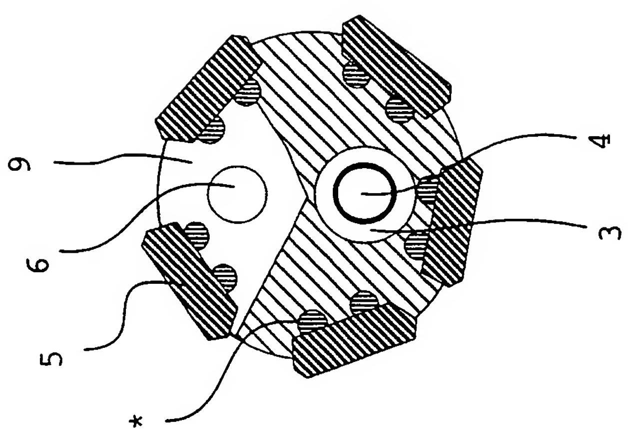
Fig. 2A

Fig. 2B

Fig. 2C

Fig. 2D

Figure.2E



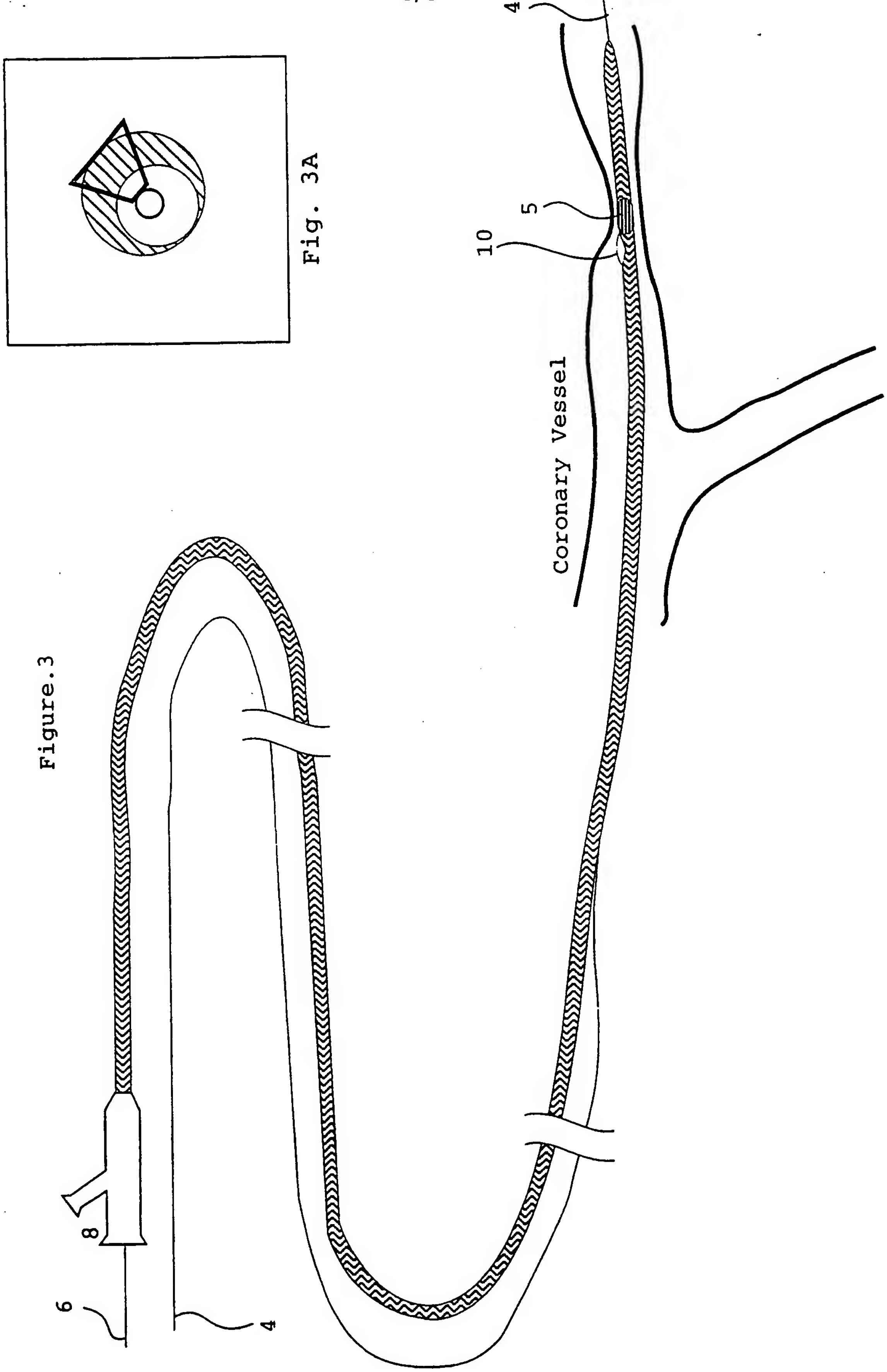


Fig. 3A

Figure.3

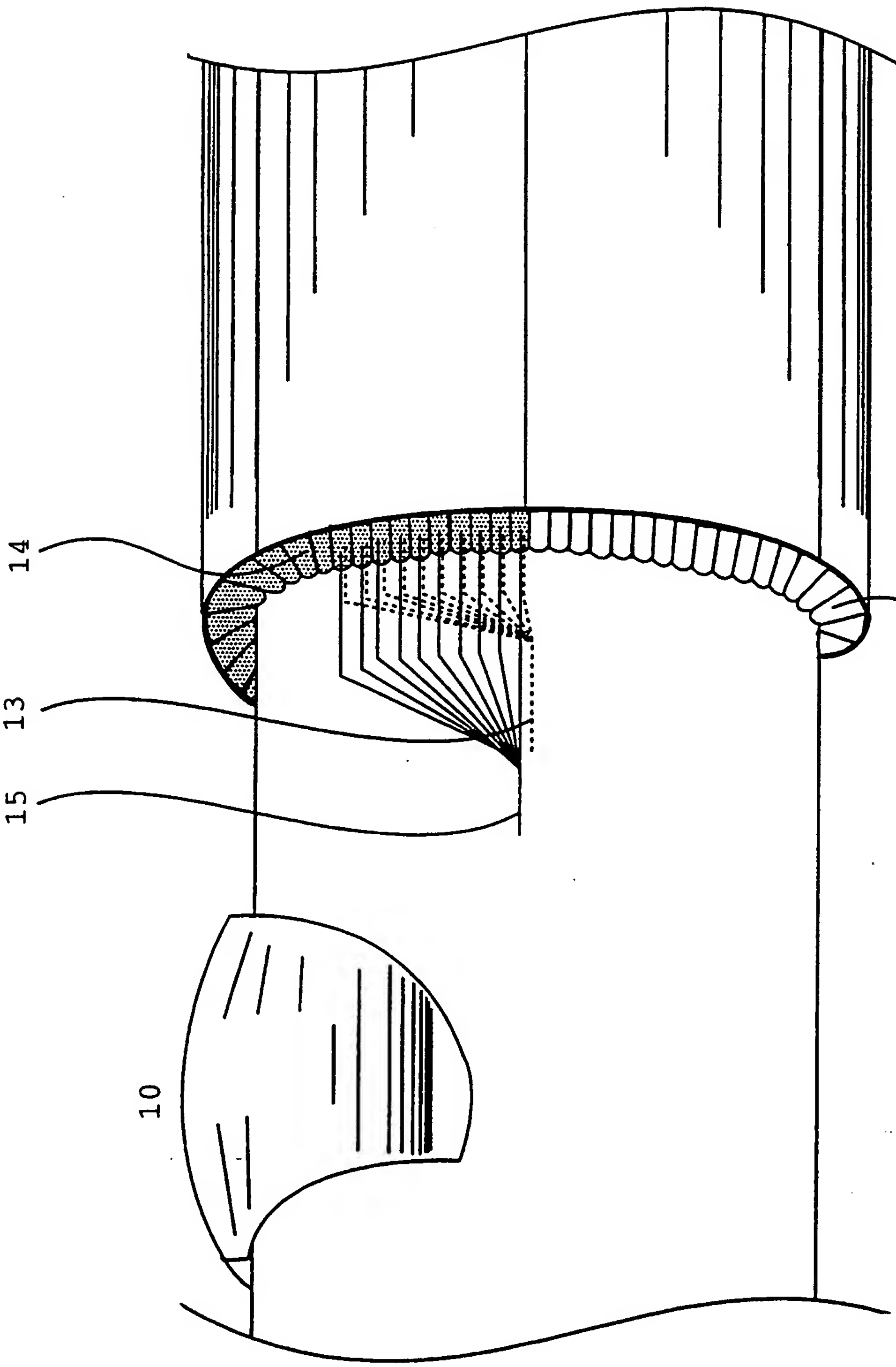


Figure 4

INTERNATIONAL SEARCH REPORT

International Application No
PCT/IB 98/01363

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61N5/10

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 A61N

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	DE 91 02 312 U (WEIKL) 25 June 1992 see page 6, line 9 - line 33; figures 1,3 ---	1,3
X	WO 95 19807 A (THE TRUSTEES OF COLUMBIA UNIVERSITY) 27 July 1995 see abstract see page 11, line 36 - page 12, line 32 see page 15, line 10 - line 27 ---	1,2
A	WO 97 18012 A (LOCALMED) 22 May 1997 see page 22, line 13 - line 15 -----	1

☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

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"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
11 December 1998	21/12/1998

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..formation on patent family members

Inter. ...nal Application No
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Patent document cited in search report	Publication date	Patent family member(s)	Publication date
DE 9102312 U	25-06-1992	NONE	
WO 9519807 A	27-07-1995	US 5503613 A	02-04-1996
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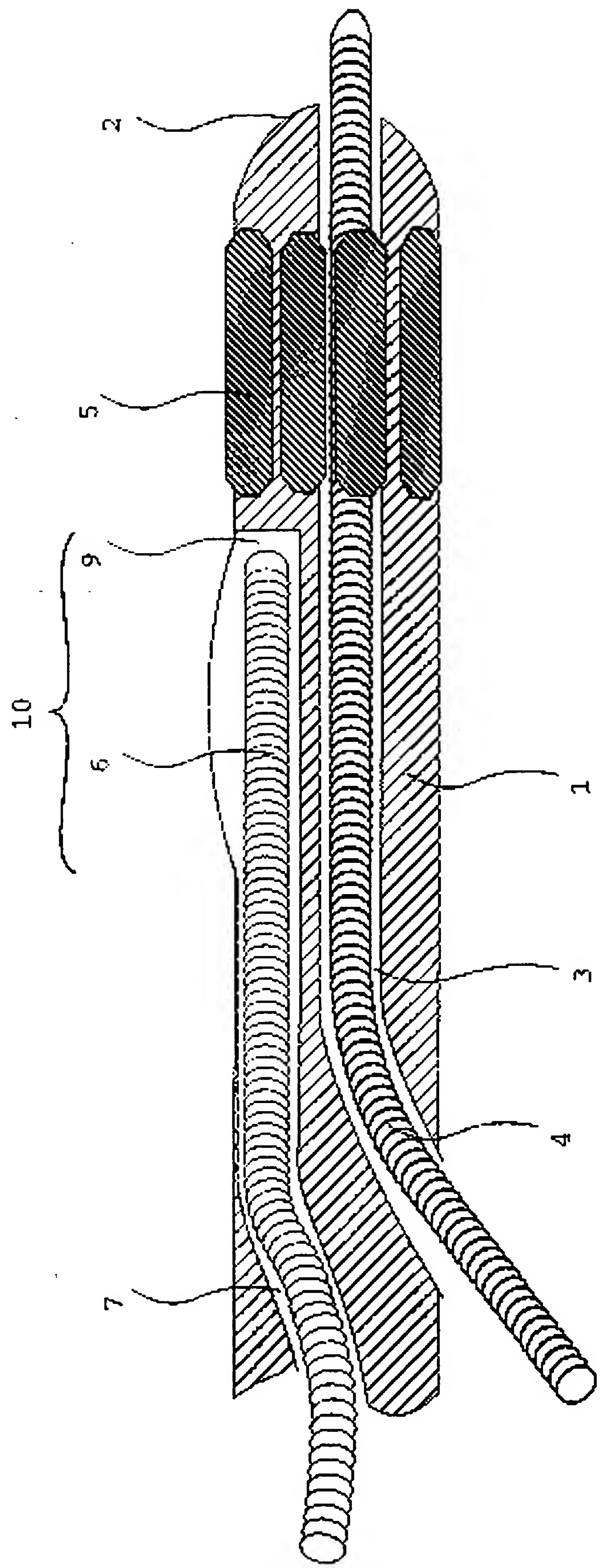

Fig.1

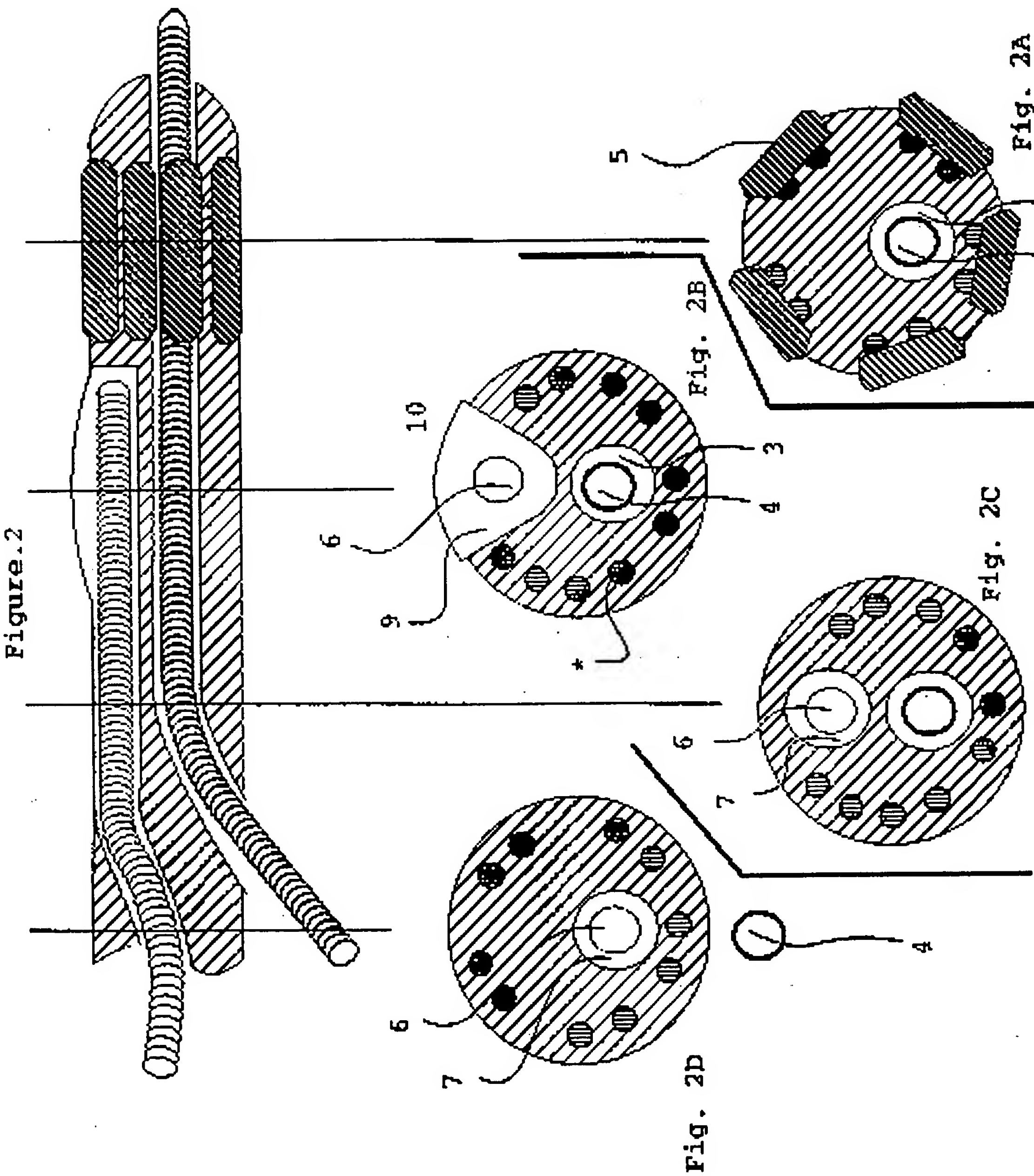

Figure.2

Fig. 2A

Fig. 2B

Fig. 2C

Fig. 2D

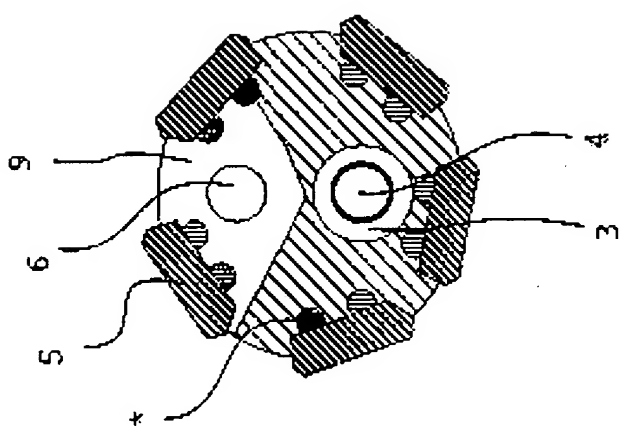

Figure.2E

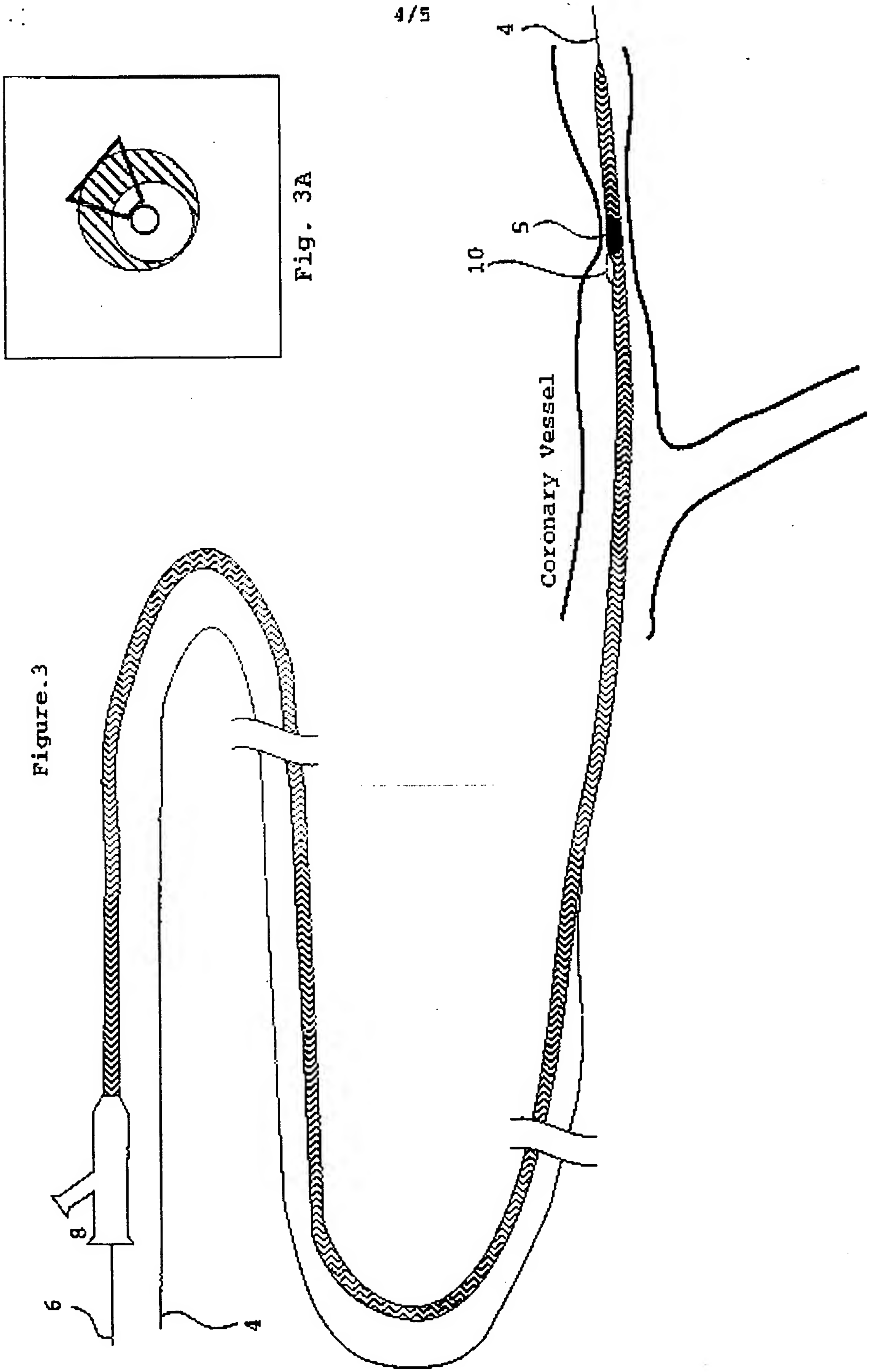

Fig. 3A

Figure.3

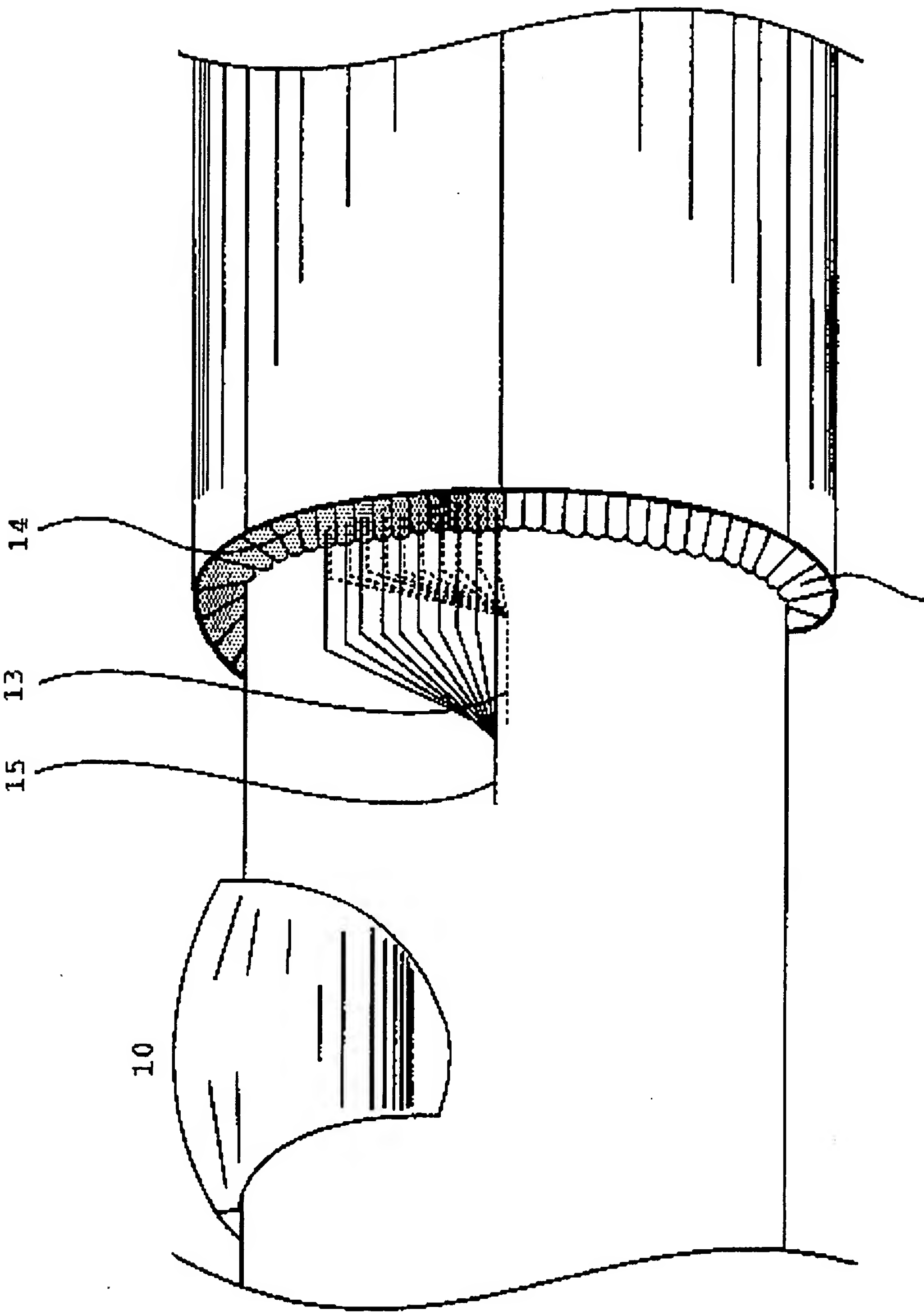

Figure 4